REMARKS

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-55 are pending. Claims 1-3 and 55 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

Support for the amended claim recitations is found throughout the specification.

II. RESPONSE TO RESTRICTION REQUIREMENT

The February 21, 2002 Office Action required an election under 35 U.S.C. § 121 from:

Group I Claims 1-36 and 45 drawn to a combined enteric composition and kit, classified in class 424, subclass 203.1;

Group II Claims 37-43 drawn to a method of immunizing classified in class 435, subclass 7.1;

Group III Claims 44 and 45 drawn to a method of preparing a composition comprising antigens, classified in class 435, subclass 69.3; and,

Group IV Claims 46-47 and 53-54 drawn to hyperimmunized colostrum and a method of preparing, classified in class 424, subclass 184.1.

The February 21, 2002 Office Action also required an election of a species, specifically from bovine, canine, feline or equine species; a first antigen from the group comprising a *Cryptosporidiun parvum* antigen, either a single antigen or a mixture and if Applicant elects a

mixture, the specific antigens included in the mixture; a second enteric enteric antigen, either a single antigen or mixture from the group consisting of *E. coli*, rotavirus, coronavirus, *Clostridium* species and mixtures thereof and if Applicant elects a mixture, at least two antigens must be elected; and a mode of presentation of the combined composition as recited in claims 1 and 9.

Applicants provisionally elect, with traverse, for further prosecution in this application, the invention of Claims 1-36 and 45 drawn to a combined enteric composition and kit, classified in class 424, subclass 203.1. Applicants also provisionally elect, with traverse, the species bovine, and elect a first antigen of P21 and a second antigen of Cp15/60, wherein the mode of presentation is in antigen form (i.e. vectors are not elected). Reconsideration and withdrawal of the restriction requirement and species election are respectfully requested in view of the remarks herewith.

The present invention relates to the fields of immunology and vaccine technology. The present claims, therefore, represent a web of knowledge and continuity of effort that merit examination in a single application. Indeed, the claims of all the Groups are related since the claims of the Groups are directed to antigens or epitopes of *Cryptosporidium parvum* and/or enteric pathogens, compositions and methods comprising or using the same for eliciting an immune response against, or for prevention, treatment, or control of *Cryptosporidium parvum* and/or enteric infections, and uses thereof.

The Office Action states that the inventions are distinct because Groups I and II are related as product and process of use, Groups I and III are related as process of making and product made, and Groups I and IV are drawn to different products. Applicants respectfully disagree with this assessment.

Rather, the claims of Groups I-IV all relate to the fields of immunology and vaccine technology, such that the claims of all four groups should be searched together.

In this regard, the Examiner's attention is respectfully requested to review MPEP § 808.02 which states, "even with patently distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

1. Separate classification;
2. Separate status in the art; or
3. Different field of search[.]"

Contrary to the guideline mandated by the MPEP, the claims of all the Groups involve the antigens or epitopes of *Cryptosporidium parvum* and/or enteric pathogens, compositions and methods comprising or using the same for eliciting an immune response against, or for prevention, treatment, or control of *Cryptosporidium parvum* and/or enteric infections, and uses thereof, thereby encompassing the same field of search. Thus, restriction is not appropriate.

More specifically, contrary to the guideline mandated by the MPEP, the claims of Groups I and IV are related since the claims in both groups are classified in class 424, and the claims of Groups II and III are all classified in class 435. Consequently, at the very least, the claims of Group IV should be rejoined with those of Group I.

Additionally, the Examiner's attention is further respectfully invited to review the text of MPEP § 803 which in part states:

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Thus, the mere allegation that the Groups identified in the Office Action are distinct does not require restriction. Rather, a showing must be made that to search all of the claims would constitute an undue burden on the Examiner. In the instant application, the Examiner has only stated that an undue burden would occur, without stating any reasons for this. Consequently, the necessary showing has not been made, such that restriction is improper.

The Office Action also required a restriction to a single species, a single disclosed first and second antigen and a mode of presentation of such antigens. It is respectfully pointed out to the Examiner that claims 2 and 7 of the present application serve as linking claims between the species. Consequently, should either or both of these claims be allowed, it is respectfully requested that the species be rejoined.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between the claims of all the Groups. Indeed, the search and examination of each Group is likely

to be co-extensive and, in any event; would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction are requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A combined [enteric] immunological, immunogenic or vaccine composition comprising a first antigen or epitope of interest from a first enteric pathogen comprising *Cryptosporidium* and/or a first vector that expresses the first antigen or epitope of interest, and a second antigen or epitope of interest from [another] a second enteric pathogen and/or the first vector that expresses the first antigen or epitope of interest also expresses the second antigen or epitope of interest and/or a second vector that expresses the second antigen or epitope of interest, and a pharmaceutically acceptable vehicle.

2. (Amended) The composition according to claim 1 comprising an antigen from *Cryptosporidium parvum* and an antigen from [another] a second enteric pathogen.

3. (Amended) The composition according to claim 2 comprising an antigen from *Cryptosporidium* and an antigen from [another] a second enteric pathogen [of a bovine species] wherein the second enteric pathogen is a pathogen of a bovine species.

55. (Amended) A method of using a first antigen or epitope from *Cryptosporidium* and/or a vector that expresses such antigen or epitope, and a second antigen or epitope from [another] a second enteric pathogen and/or a vector that expresses such antigen or epitope, for the preparation of an immunogenic or vaccine composition against enteric infections, comprising admixing the first antigen or epitope and/or vector and the second antigen or epitope and/or vector.